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JANUARY–JUNE 1989 VOLUME 33

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Coming next month . . .

Genital surgery

Gynecologic uses of the CO_2 laser have proliferated. The July symposium focuses on the external genitalia, perineum, and perianal region.

Pelvic endometriosis

When minimal implants are diagnosed, observe the patient who is trying to become pregnant for 6 months or so, rather than treat her immediately.

Multiple sclerosis

Since this disease strikes women of reproductive age, be prepared to answer questions about its relationship with pregnancy and gynecologic disorders.

Nonrheumatoid arthritis

These disparate diseases respond to a wide assortment of medications. When the patient is pregnant, though, carefully weigh side effects before prescribing or maintaining a regimen.

Look for these and other important articles in the July CONTEMPORARY OB/GYN

vaginal cream 2%
Femstat Prefill
(butoconazole nitrate)

BRIEF SUMMARY

INDICATIONS: FEMSTAT® (butoconazole nitrate) vaginal cream 2.0% is indicated for local treatment of vulvovaginal mycotic infections caused by Candida species. Confirm the diagnosis by KOH smears and/or cultures. FEMSTAT can be used with oral contraceptives and antibiotics. It is effective in non-pregnant women and during the second and third trimesters of pregnancy.

CONTRAINDICATIONS: FEMSTAT is contraindicated in patients hypersensitive to any of the ingredients.

PRECAUTIONS: General: If clinical symptoms persist, repeat microbiological tests to rule out other pathogens and confirm the diagnosis. Discontinue drug if sensitization or irritation occurs.

Information for the Patient: Do not discontinue prematurely during menstruation or because of symptomatic relief.

Carcinogenesis: Animal studies have not been done.

Mutagenesis: Mutagenicity studies were negative.

Impairment of Fertility: Animal studies showed no impairment of fertility.

Pregnancy Category C: Adverse effects were noted in animals treated with high oral doses. No studies were done in women during first trimester. Patients in the second or third trimester have shown no adverse effects attributable to the drug.

Nursing Mothers: Use with caution.

Pediatric Use: Safety and efficacy have not been established.

ADVERSE REACTIONS: Vulvar/vaginal burning in 2.3% of patients, vulvar itching in 0.9%, discharge, soreness, swelling, itching of fingers each in 0.2%. Complaints caused 1.6% to discontinue drug.

DOSAGE AND ADMINISTRATION:
Non-pregnant Patients: The recommended dose is one applicatorful of cream (approximately 5 grams) intravaginally at bedtime for three days. Treatment can be extended for an additional three days if necessary.

Pregnant Patients (second and third trimesters only): The recommended dose is one applicatorful of cream (approximately 5 grams) intravaginally at bedtime for six days.

CAUTION:
Federal law prohibits dispensing without prescription.

SYNTEX
SYNTEX LABORATORIES, INC.
PALO ALTO, CA 94304

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

TIMENTIN® **sterile ticarcillin disodium and clavulanate potassium** for Intravenous Administration

INDICATIONS AND USAGE: TIMENTIN® is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

Bacterial Septicemia: including bacteremia, caused by β-lactamase producing strains of *Klebsiella* spp., *E. coli, Staphylococcus aureus* and *Pseudomonas aeruginosa* (and other *Pseudomonas* species). Lower Respiratory Infections: caused by β-lactamase producing strains of *Staphylococcus aureus, Hemophilus influenzae* and *Klebsiella* spp. Bone and Joint Infections: caused by β-lactamase producing strains of *Staphylococcus aureus.* Skin and Skin Structure Infections: caused by β-lactamase producing strains of *Staphylococcus aureus, Klebsiella* spp., and *E. coli.* Urinary Tract Infections (complicated and uncomplicated): caused by β-lactamase producing strains of *E. coli, Klebsiella* spp., *Pseudomonas aeruginosa* (and other *Pseudomonas* species), *Citrobacter* spp., *Enterobacter cloacae, Serratia marcescens*, and *Staphylococcus aureus* . Gynecologic Infections: Endometritis caused by β-lactamase producing strains of *B. melaninogenicus; Enterobacter* spp. (including *E. cloacae**), *Escherichia coli, Klebsiella pneumoniae; Staphylococcus aureus,* and *Staphylococcus epidermidis.*

While TIMENTIN is indicated only for the conditions listed above, infections caused by ticarcillin susceptible organisms are also amenable to TIMENTIN treatment due to its ticarcillin content. Therefore, mixed infections caused by ticarcillin susceptible organisms and β-lactamase producing organisms susceptible to TIMENTIN should not require the addition of another antibiotic.

ADVERSE REACTIONS: As with other penicillins, the following adverse reactions may occur: *Hypersensitivity reactions:* skin rash, pruritus, urticaria, arthralgia, myalgia, drug fever, chills, chest discomfort, and anaphylactic reactions. *Central nervous system:* headache, giddiness, neuromuscular hyperirritability or convulsive seizures. *Gastrointestinal disturbances:* disturbances of taste and smell, stomatitis, flatulence, nausea, vomiting and diarrhea, epigastric pain. *Hemic and Lymphatic systems:* thrombocytopenia, leukopenia, neutropenia, eosinophilia and reduction of hemoglobin or hematocrit. Prolongation of prothrombin time and bleeding time. *Abnormalities of hepatic and renal function tests:* elevation of serum aspartate aminotransferase (SGOT), serum alanine aminotransferase (SGPT), serum alkaline phosphatase, serum LDH, serum bilirubin. Rarely, transient hepatitis and cholestatic jaundice–as with some other penicillins and some cephalosporins. Elevation of serum creatinine and/or BUN, hypernatremia. Reduction in serum potassium and uric acid. *Local reactions:* pain, burning, swelling and induration at the injection site and thrombophlebitis with intravenous administration. *Overdosage:* As with other penicillins, TIMENTIN in overdosage has the potential to cause neuromuscular hyperirritability or convulsive seizures. Ticarcillin may be removed from circulation by hemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with information from a single patient with renal insufficiency all suggest that this compound may also be removed by hemodialysis.

CONTRAINDICATIONS: TIMENTIN is contraindicated in patients with a history of hypersensitivity reactions to any of the penicillins.

WARNINGS: SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTOID) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH TIMENTIN, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OR OTHER DRUGS. IF AN ALLERGIC REACTION OCCURS, TIMENTIN SHOULD BE DISCONTINUED AND THE APPROPRIATE THERAPY INSTITUTED. **SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE PROVIDED AS INDICATED.**

PRECAUTIONS: While TIMENTIN possesses the characteristic low toxicity of the penicillin group of antibiotics, organ system functions should be assessed periodically during therapy.

Bleeding manifestations have occurred in some patients receiving β-lactam antibiotics. These reactions have been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time and are more likely to occur in patients with renal impairment. If bleeding manifestations appear, TIMENTIN treatment should be discontinued and appropriate therapy instituted.

TIMENTIN has only rarely been reported to cause hypokalemia. Periodic monitoring of serum potassium may be advisable in patients receiving prolonged therapy.

Pregnancy (Category B): Reproduction studies have been performed in rats given doses up to 1050 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to TIMENTIN. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

DOSAGE AND ADMINISTRATION: TIMENTIN should be administered by intravenous infusion (30 min.). Usual recommended dose for systemic and urinary tract infections for average (60 kg) adults is 3.1 Gm TIMENTIN (3.1 Gm vial containing 3 Gm ticarcillin and 100 mg clavulanic acid) given every 4 to 6 hours. For gynecologic infections TIMENTIN should be administered as follows: Moderate infections 200 mg/kg/day in divided doses every 6 hours and for severe infections 300 mg/kg/day, based on ticarcillin content, in divided doses every 4 hours. For patients weighing less than 60 kg, the recommended dosage is 200-300 mg/kg/day, based on ticarcillin content, given in divided doses every 4 to 6 hours. In urinary tract infections, a dosage of 3.2 Gm TIMENTIN (3.2 Gm vial containing 3 Gm ticarcillin and 200 mg clavulanic acid) given every 8 hours is adequate. Please see official package insert for details on dosages for other patients, including those with renal insufficiency, and directions for use.

SUPPLIED: 3.1 Gm and 3.2 Gm Standard Vials; 3.1 Gm and 3.2 Gm Piggyback Bottles; 31 Gm Bulk Pharmacy Package; 3.1 Gm ADD-Vantage™ Antibiotic Vial.

*Efficacy for this organism in this organ system was studied in fewer than 10 infections. 7548/H–BS ©1989, Beecham Laboratories

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